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| 10/821,828 | 04/09/2004 | Hector F. DeLuca | 1256-00949 | 1399 |
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| ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202 | | | EXAMINER BADIO, BARBARA P | |
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| | | | 1617 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,828

Applicant(s)

DELUCA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-71 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/26/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 55 and 59-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Art Unit: 1617

The instant claims are drawn to a method of treating an "autoimmune disease" by administering the claimed compound(s). Autoimmune disease is inclusive of a number of diseases such as AIDS and multiple sclerosis. Because of the complexity of the human body and the differences in the underlining cause(s) of the various diseases that are encompassed by the phrase "autoimmune disease" and the lack of showing in the medical art of the utilization of a single agent in the treatment of all autoimmune diseases, the skilled artisan in the art at the time of the present invention would doubt the claimed compounds would be useful in the treatment of every autoimmune disease, known and unknown, as encompassed by the instant claims. Therefore, in order to practice the claimed invention, the skilled artisan in the art at the time of the present invention would have to first determine the effect of the claimed compounds in the treatment of every autoimmune disease. Because of the knowledge in the medical art, the quantity of experimentation necessary to practice the claimed invention would be undue.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-11, 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims lack a period and, thus, are indefinite.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035).

Each of 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 teaches 2-alkylidene-19-nor vitamin D compounds useful in treating (a) metabolic bone diseases

Art Unit: 1617

such as osteoporosis, osteomalacia etc., (b) psoriasis; (c) cancers such as leukemia, colon cancer, etc. and (d) immune diseases such as multiple sclerosis and diabetes (see each in its entirety, especially claims).

The instant claims differ from the cited references in that they recite the 18-nor derivatives of the cited patents. However, (a) Bishop et al. (US 5,972,917) teaches an equivalent between hydrogen and methyl in the 18-position of vitamin derivatives (see col. 5, formula (II), definition of X) and (b) Deluca et al. teaches 18,19-dinor vitamin D derivatives show a preferential activity on intestinal calcium transport with reduced calcium mobilizing activity in bone (see page 5, lines 4-10). The compounds of Bishop and Deluca are taught to be useful in treating similar diseases such as cancer, psoriasis, multiple sclerosis, bone loss (see for example, '917, col. 9, line 54 – col. 10, line 32; '035, page 5, lines 10-14; page 24, lines 30-35; pages 25-28, Biological activity of 18,19-dinor-vitamin D compounds). Based on the combined teachings of the cited references, the instant claims are rendered obvious.

7. Claims 1, 22, 28-32, 34-38, 40-45, 47-53, 55-62 and 64-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 and 59-67 of U.S. Patent No. 7,238,681. Although the conflicting claims are not identical, they are not patentably distinct from each other because both encompass 2-methylene-18,19-dinor-1 α -hydroxy-homopregnacalciferol as defined by the cited patent. Unlike the instant claims, the claims of the cited patent are limited in scope. However, the claimed compounds are recited/disclosed by the claims and disclosure of

Art Unit: 1617

the cited patent and, thus, are anticipated (see for example, compounds of claims 1 and 8).

8. Claims 1-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/530,903; 10/544,163; 10/997,698 and 11/351,874 in view of in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035).

Each of 10/530,903; 10/544,163; 10/997,698 and 11/351,874 teaches 2-alkylidene-19-nor vitamin D compounds useful in treating various diseases including multiple sclerosis, inflammatory bowel diseases, psoriasis and cancer (see for example 11/351,874, claims 8-12; 10/530,903, claim 5).

The instant claims differ from the cited copending applications by the recitation of the corresponding 18,19-dinor derivatives. However, (a) Bishop et al. (US 5,972,917) teaches an equivalent between hydrogen and methyl in the 18-position of vitamin derivatives (see col. 5, formula (II), definition of X) and (b) Deluca et al. teaches 18,19-dinor vitamin D derivatives show a preferential activity on intestinal calcium transport with reduced calcium mobilizing activity in bone (see page 5, lines 4-10). The compounds of Bishop and Deluca are taught to be useful in treating similar diseases such as cancer, psoriasis, multiple sclerosis, bone loss (see for example, '917, col. 9, line 54 – col. 10, line 32; '035, page 5, lines 10-14; page 24, lines 30-35; pages 25-28, Biological activity of 18,19-dinor-vitamin D compounds). Based on the combined teachings of the cited references, the instant claims are rendered obvious.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (WO 96/16035).

Deluca et al. teaches several compounds useful in the synthesis of 18,19-dinor-vitamin D compounds (see the entire article, especially page 9, compounds VII, VIII, IX and III; page 22, scheme I, compounds 6-13).

The instant claims differ from the reference by reciting isomers of the exemplified prior art compounds, i.e., the corresponding 20S of the prior art compounds. However, the reference teaches production of both 20(R) and 20(S)-18,19-dinor-vitamin D compounds as well as both isomeric forms of the compounds used in their production (see page 3, lines 5-16; page 7, lines 29-30). Therefore, it would have been obvious to the skilled artisan in the art to modify the process exemplified by the reference by utilizing the 20-S isomers of the prior art compounds with the reasonable expectation of obtaining the corresponding 20-epi (20S)-18,19-dinor-vitamin D compounds.

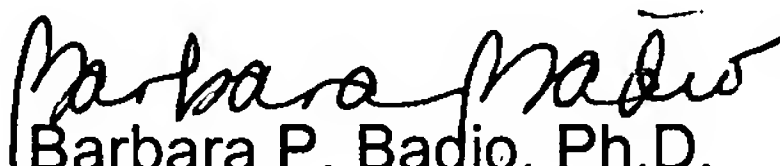
Art Unit: 1617

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
July 23, 2007